NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

WYETH,	:	**Civil Action No.: 09-3235 (FLW)**
Plaintiff,	:	
v.	:	**MEMORANDUM OPINION AND ORDER**
ORGENUS PHARMA INC., et al.,	:	
Defendants.	:	

ARPERT, U.S.M.J.

This matter comes before the Court on a Motion by Defendants Orgenus Pharma Inc. and Orchid Chemical & Pharmaceuticals Ltd. (collectively, "Defendants" or "Orchid") to compel Plaintiff Wyeth ("Plaintiff" or "Wyeth") to produce certain license agreements and settlement agreements [dkt. entry no. 69]. Wyeth has objected to production of these materials on the grounds of irrelevancy and that third parties maintain a confidentiality interest in these settlement related agreements. The Court has fully reviewed the parties' written submissions and conducted oral argument on August 24, 2010. For the reasons set forth below, Defendants' Motion to compel is granted.

I. BACKGROUND AND PROCEDURAL HISTORY

On July 2, 2009, Wyeth filed a Complaint alleging that Defendants' Abbreviated New Drug Application ("ANDA") No. 91-123, which seeks approval to market a generic copy of Wyeth's Effexor XR®, an extended release dosage form containing venlafaxine hydrochloride used to treat depression and other psychiatric disorders, infringes claims 20-25 of U.S. Patent No. 6,274,171 B1 ("the '171 Patent"), claims 1-6 of U.S. Patent No. 6,419,958 B2 ("the '958 Patent"), and claims 1,

2, 13, and 14 of U.S. Patent No. 6,403,120 B1 ("the '120 Patent") (collectively, the "patents-in-suit"). Ultimately, Wyeth seeks to have the Court enjoin Defendants from commercially manufacturing, using, offering for sale, or selling their ANDA 91-123 product until the expiration of the patents-in-suit in September 2017.

Since the approval of Effexor XR® in July 2000, sixteen (16) generic challengers have sought to copy Wyeth's drug. (Pl.'s Opp'n Br. at 2) Pursuant to the provisions of the Hatch-Waxman Act, Wyeth has brought suit against each generic challenger alleging infringement of its patents which cover extended release venlafaxine formulations, including Effexor XR®. *Id*. Wyeth has previously settled at least nine (9) of these cases. (Def.'s Br. at 1-2) In this case, a dispute has arisen over Wyeth's refusal to produce the settlement agreements and license agreements associated with the settlement of other litigation related to the patents-in-suit. Defendants have filed the instant application to compel production of these agreements.

A. Defendants' Arguments in Support of their Motion to Compel

Defendants offer four (4) reasons why the Court should compel Wyeth to produce all settlement agreements and license agreements related to the patents-in-suit. Defendants argue that these agreements are directly relevant to (1) Defendants' invalidity defenses, (2) Wyeth's claim for injunctive relief, (3) potential damages in the event Defendants launch their product following the expiration of the 30-month stay, and (4) the potential availability of a patent misuse defense. *Id.* at 1.

Defendants first argue that the documents they seek are relevant to their defenses and are likely to lead to the discovery of admissible evidence; specifically, evidence related to their invalidity defenses under 35 U.S.C. §103. *Id*. at 4. Defendants draw parallels to *Datapoint Corp. v. Picturetel Corp,* No. 93-2381, 1998 WL 51356, at *2 (N.D. Tex. Jan. 23, 1998), where the defendant moved

to compel plaintiff to produce "a license agreement reached as part of a settlement of litigation" in an unrelated case. *Id*. at *1. In *Datapoint*, the license agreement contained a confidentiality provision prohibiting disclosure of the terms of settlement absent a court order. *Id*. at *2. Ultimately, the *Datapoint* Court held:

> There is good cause for the court to exercise its discretion and order disclosure of the settlement terms because this information appears reasonably calculated to lead to the discovery of admissible evidence. At a minimum, this evidence could demonstrate patent validity . . . Fed. R. Evid. 408 likewise recognizes the admissibility of evidence of settlement communications for purposes other than proving liability for or invalidity of the claim or its amount.

No. 93-2381, 1998 WL 51356, at * 2.

Defendants also argue that the license agreements are relevant to Wyeth's request for injunctive relief. Defendants support this argument by citing *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831 (Fed. Cir. 2010) explaining that the Circuit Court recognized that past licensing practices are a pertinent consideration in the evaluation of whether irreparable injury would occur in the absence of an injunction. (Def.'s Br. at 6) Defendants argue that "the license agreements also would be pertinent to the issue of potential damages in the event Orchid launches its generic product 'at risk' upon FDA final approval . . . [thus,] [i]n sum, Orchid has the right to analyze the previous license agreements and settlement agreements now in order to plan its business and litigation strategy in consideration of an 'at risk' launch of its product." *Id.* at 6-7.

Further, Defendants argue that "the license agreements and settlement agreements bear on the issue of whether Wyeth has entered into any settlement arrangements that unduly restrict competition and, as a consequence, could form the basis for a patent misuse defense." *Id*. at 7. Defendants draw analogies to *Key Pharm., Inc. v. ESI-Lederle, Inc.,* No. 96-1219, 1997 WL 560131,

at *2-4 (E.D. Pa. Aug. 29, 1997), a case in which defendant filed an ANDA seeking to sell an extended release version of plaintiff's potassium chloride product and later moved to compel production of a settlement agreement from earlier litigation, where the court held that plaintiff has the right to discovery of prior settlement agreements in order to explore the viability of a patent misuse defense. *Id.* Ultimately, Defendants argue that they are "entitled to explore the availability of any and all defenses pertinent to Wyeth's patent infringement claims." *Id*. (*citing* FED. R. CIV. P. 26(b)(1)).

Finally, Defendants argue that "confidentiality agreements between private parties cannot affect the discoverability of agreements, that private parties cannot limit the Court's authority to compel production of relevant documents in a subsequent litigation," and that "[h]ere, the Discovery Confidentiality Order already in place provides sufficient protection to render Wyeth's confidentiality objection moot." *Id.* at 8-10 (citations omitted).

B. Plaintiff's Arguments Opposing Defendants' Motion to Compel

In opposing the Motion, Wyeth sets forth four (4) reasons why it should be denied, including

> (1) the settlement agreements are not relevant to validity because Wyeth is not relying on them to refute Orchid's invalidity claims;
>
> (2) the ultimate relief available to Wyeth is spelled out in the Hatch-Waxman Act and Wyeth's prior settlements (particularly the terms of those agreements) are irrelevant to Wyeth's entitlement to injunctive relief;
>
> (3) the agreements are not relevant to damages as there is no claim for damages; and
>
> (4) the agreements are similarly not relevant to a defense of patent misuse since no such defense has been asserted.

(Pl.'s Opp'n Br. at 1)

Wyeth argues that the settlement agreements are not relevant to patent validity in this case, stating, "Orchid first asserts that the agreements are relevant to the issue of obviousness of the patents-in-suit [but] . . . ignores that this is only true in situations where the patentee relies on or plans to rely on such agreements as evidence of non-obviousness . . . [, and here,] Wyeth has no intention of relying on its agreements as evidence of non-obviousness." *Id*. at 5-6. Instead, Wyeth asserts that it will rely on the clinical advantages of Effexor XR® and its commercial success. *Id*. Therefore, Wyeth argues, because it will not rely on prior settlements and licenses, the cases Defendants rely on are inapplicable. *Id*. Wyeth specifically notes that Defendants' reliance on *Datapoint* is misplaced because "[t]he mere fact that, [i]n this case, Orchid, like the *Datapoint* defendant, has asserted invalidity defenses, does not open up limitless discovery into Wyeth's business dealings and information regarding Orchid's competitors, and *Datapoint* does not support such a result." *Id*. at 7.

Wyeth also argues that the agreements are not relevant to Wyeth's entitlement to injunctive relief in this case. Wyeth points out that "the Hatch-Waxman Act explicitly provides the remedies available to Wyeth should it prevail, [s]pecifically, Wyeth's ultimate remedy would be an order that FDA approval of Orchid's ANDA shall be no earlier than the expiration date of Wyeth's patents and a permanent injunction barring Orchid from selling its infringing generic version of Effexor XR®." *Id.* Wyeth argues that "[its] prior settlements have no bearing on its entitlement to this statutory relief [n]or is a preliminary injunction proceeding looming on the horizon." *Id*.

Wyeth further argues that Defendants have not raised a claim or defense of patent misuse in this case and "its assertion that it should be permitted discovery of Wyeth's settlement agreements in order to conjure up such a claim is a classic example of the type of fishing expedition disallowed by this Court and many others." *Id.* at 8-9 (citations omitted).

Finally, Wyeth argues that "[w]eighed against Orchid's baseless assertions of relevance, the policy concerns underlying Rule 408 and Rule 26 of the Federal Rules of Evidence and Civil Procedure heavily weigh in favor of a denial of Orchid's [M]otion to compel production here." *Id.* at 11. Wyeth asserts that the information contained in the agreements sought "is not relevant to any claim or defense actually asserted in this case, and the possible disclosure of information, as detailed below, may have a significant negative impact on the business of those third parties." *Id.* at 12. Wyeth contends that if settlement and license agreements are produced, information regarding the "royalty that its competitors will be paying will give Defendants an unfair advantage in pricing its drug, including insight into its competitors' floor price." *Id.* at 13. Wyeth claims that disclosure of this sensitive information may ultimately have antitrust implications because it will enable Defendants "to understand or predict the likely competitive responses of others in their market, because such an exchange may facilitate express or tacit collusion to increase prices or otherwise reduce competition." *Id.*

III. DISCUSSION

A. Federal Rule of Civil Procedure 26(b)(1)

Pursuant to FED. R. CIV. P. 26(b)(1), "parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense" and "the court may order discovery of any matter relevant to the subject matter involved in the action", although "relevant information need not be admissible at trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence". Although relevant information need not be admissible at trial, courts will refuse to compel discovery if the information being sought is (1) irrelevant to the claim, or (2) protected by a recognized privilege. *Id.*; *see also Pearson v. Miller*, 211 F.3d 57, 65 (3d Cir. 2000). Federal Rule 37(a) allows a party to file a motion to compel production where the

opposing party fails to respond adequately to a document request propounded pursuant to Rule 34. *See* FED. R. CIV. P. 37(a)(3)(B)(iv). Ultimately, it is within the discretion of the district court to grant a motion to compel disclosure for good cause shown. (*See In re Cendant Corp. Sec. Litig.*, 343 F. 3d 658, 661 (3d Cir. 2003))

B. Relevance of Requested Documents

The documents that are the subject of the instant Motion to compel include license agreements and settlement agreements related to the settlement of prior litigation involving the patents-in-suit. Having considered the parties' arguments, the Court finds that the subject agreements are discoverable as Defendants' request for their production is reasonably calculated to lead to the discovery of admissible evidence concerning Plaintiff's patent validity claims and/or Defendants' invalidity defenses. The Court also finds that the license agreements and settlement agreements may lead to the discovery of admissible evidence on the question of the damages Plaintiff might sustain in the event Defendants were to launch a generic version of Effexor XR®. The Court finds that the requested documents may be relevant to Defendants' evaluation of the viability of a patent misuse defense as well as to the issues of invalidity and obviousness under 35 U.S.C. §103.

The Court notes that other courts have routinely recognized that license agreements relating to the patent-in-suit, and entered into in connection with settlement, are discoverable and that Plaintiff's third party confidentiality concerns do not outweigh legitimate grounds to compel production. (*See Phoenix Solutions Inc. v. Wells Fargo Bank, N.A.*, 254 F.R.D. 568, 582-83 (N.D. Cal. 2008); *Datapoint Corp. v. Picturetel Corp.*, 1988 WL 51356, at *2 (N.D. Tex. 1998); *Key Pharm., Inc., v. ESI-Lederle, Inc.*, 1997 WL 560131, at *2-4 (E.D. Pa. 1997); *Am. Standard, Inc. v. Pfizer, Inc.*, 1988 WL 156152, at *2 (S.D. Ind. 1988); *Datatreasury Corp. v. Wells Fargo & Co.*,

2010 WL 903259, at *2 (E.D. Tex. 2010); *Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 768-69 (Fed. Cir. 1988); *EWP Corp. v. Reliance Universal, Inc.*, 755 F.2d 898, 908 (Fed. Cir. 1985); *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *i4i Ltd. P'Ship v. Microsoft Corp.*, 598 F.3d 831 (Fed. Cir. 2010); *ResQNet.com, Inc. v. Lansa, Inc.* 594 F.3d 860, 872 (Fed. Cir. 2010); *Tyco Healthcare Group LP v. E-Z-EM, Inc.*, 2010 WL 774878, at *2 (E.D. Tex. 2010); *Semiconductor Energy Lab. Co. v. Chi Mei Optoelectronics Corp.*, 2006 WL 3826726, at *3 (N.D. Cal. 2006); *Thomas & Marker Constr. Co. v. Wal-Mart Stores, Inc.*, 2008 WL 3200642, at *3 (S.D. Ohio 2008); *Sonnino v. Univ. of Kan. Hosp. Auth.*, 2004 WL 769325, at *3 (D. Kan. 2004); *Koch Indus., Inc. v. Columbia Gas Transmission Corp.*, 1990 WL 72789, at *1-2 (E.D. La. 1990); *Gutter v. E.I. DuPont De Nemours & Co.*, 2001 WL 36086590, at *1 (S.D. Fla. 2001)) Accordingly, the Court finds that the requested documents must be produced by Wyeth.

III. CONCLUSION AND ORDER

The Court having considered the papers submitted and the argument of counsel, and for the reasons set forth above,

IT IS on this 19th day of October, 2010,

ORDERED Defendants' Motion to compel Wyeth to produce of all license agreements and settlement agreements related to the settlement of other litigation based on the patents-in-suit [dkt. entry no. 69] is **GRANTED**; and it is further

ORDERED that Wyeth shall produce all license agreements and settlement agreements related to the patents at issue no later than **October 30, 2010**.

s/ *Douglas E. Arpert*
DOUGLAS E. ARPERT
UNITED STATES MAGISTRATE JUDGE